60th Medical Group (AMC), Travis AFB, CA

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC)

FINAL REPORT SUMMARY

(Please type all information. Use additional pages if necessary.)

PROTOCOL #: FDG20140039A **DATE:** 13 August 2015

PROTOCOL TITLE: Treatment of Chronic Myocardial Infarction in a Pig (*Sus scrofa*) Model with Extracellular Matrix and Stem Cells.

PRINCIPAL INVESTIGATOR (PI) / TRAINING COORDINATOR (TC): Lt Col Darren Danielson and Dr. W. Douglas Boyd

DEPARTMENT: Cardiothoracic Surgery **PHONE #:** 423-2300

INITIAL APPROVAL DATE: 4 September 2014 **LAST TRIENNIAL REVISION DATE:** N/A

FUNDING SOURCE: HQ/SGO

1. **RECORD OF ANIMAL USAGE:**

Animal Species:	Total # Approved	# Used this FY	Total # Used to Date
Sus scrofa	73	49	49

2. **PROTOCOL TYPE / CHARACTERISTICS:** (Check all applicable terms in **EACH** column)

___ Training: Live Animal	___ Medical Readiness	___ Prolonged Restraint
___ Training: non-Live Animal	___ Health Promotion	___ Multiple Survival Surgery
_X_ Research: Survival (chronic)	___ Prevention	___ Behavioral Study
___ Research: non-Survival (acute)	___ Utilization Mgt.	___ Adjuvant Use
___ Other ( )	_X__ Other (Treatment)	___ Biohazard

3. **PROTOCOL PAIN CATEGORY (USDA):** (Check applicable) ___ C _X_ D ___ E

4. **PROTOCOL STATUS:**

***Request Protocol Closure:**

___ Inactive, protocol never initiated

___ Inactive, protocol initiated but has not/will not be completed

_X_ Completed, all approved procedures/animal uses have been completed

5. **Previous Amendments:**
List all amendments made to the protocol.. **IF none occurred, state NONE. Do not use N/A.**

For the Entire Study Chronologically

Amendment Number	Date of Approval	Summary of the Change
1	6 Aug 2014	Animal use-telemetry technique development
2	21 May 2015	Personnel change PI from Danielson to Neff

6. **FUNDING STATUS:** Funding allocated: $ 32,550.00 Funds remaining: $ 0.00

7. **PROTOCOL PERSONNEL CHANGES:**

Have there been any personnel/staffing changes (PI/CI/AI/TC/Instructor) since the last IACUC approval of protocol, or annual review? _X__ Yes ___ No

If yes, complete the following sections (Additions/Deletions). For additions, indicate whether or not the IACUC has approved this addition.

ADDITIONS: (Include Name, Protocol function - PI/CI/AI/TC/Instructor, IACUC approval - Yes/No)

Maj Lucas Neff(PI), 21 May 2015

DELETIONS: (Include Name, Protocol function - PI/CI/AI/TC/Instructor, Effective date of deletion)

Lt Col Darren Danielson(PI), 21 May 2015

8. **PROBLEMS / ADVERSE EVENTS:** Identify any problems or adverse events that have affected study progress. Itemize adverse events that have led to unanticipated animal illness, distress, injury, or death; and indicate whether or not these events were reported to the IACUC.

None.

9. **REDUCTION, REFINEMENT, OR REPLACEMENT OF ANIMAL USE:**

REPLACEMENT (ALTERNATIVES): Since the last IACUC approval, have alternatives to animal use become available that could be substituted in this protocol without adversely affecting study or training objectives?

None.

REFINEMENT: Since the last IACUC approval, have any study refinements been implemented to reduce the degree of pain or distress experienced by study animals, or have animals of lower phylogenetic status or sentience been identified as potential study/training models in this protocol?

None.

REDUCTION: Since the last IACUC approval, have any methods been identified to reduce the number of live animals used in this protocol?

None.

10. **PUBLICATIONS / PRESENTATIONS:** (List any scientific publications and/or presentations that have resulted from this protocol. Include pending/scheduled publications or presentations).

11. **Were the protocol objectives met, and how will the outcome or training benefit the DoD/USAF?**

Yes. Using the model developed in protocols FDG20120019A and FDG20130043A, we were able to successfully create myocardial infarctions in pigs with a high survival rate in order to study the effect of extracellular matrix and stem cells on myocardial regeneration.

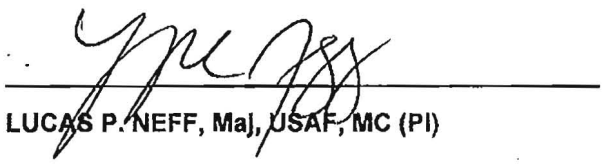
12. **PROTOCOL OUTCOME SUMMARY:** (Please provide, in "ABSTRACT" format, a summary of the protocol objectives, materials and methods, results - include tables/figures, and conclusions/applications.)

Objectives: The goal of this protocol was to create myocardial infarctions in minipigs using polystyrene microspheres to infarct a portion of the left ventricle myocardium for future regenerative medicine studies.

Methods: Castrated male Yucatan minipigs were premedicated with oral amiodarone, aspirin, and clopidogrel according to protocol. Once the pigs were anesthetized a baseline echocardiogram was obtained. Under fluoroscopic guidance, a hockey stick catheter was placed in a femoral artery into the left anterior descending (LAD) coronary artery. A guide wire was then placed in the first or second diagonal branch of the LAD, over which a coronary artery balloon catheter was advanced. Once in place, the balloon catheter was inflated and polystyrene microspheres were injected to occlude the vessel. The echocardiogram was repeated, and the pigs were recovered. Two weeks later, provided there were no postoperative complications, the pigs were transferred to UC Davis for maintenance and further surgery.

Results: Forty-nine underwent myocardial infarctions without misadventure. Infusion of polystyrene beads into a diagonal branch of the LAD resulted in a repeatable and controlled myocardial infarction.

Conclusion: The method reported here provided consistent and repeatable myocardial infarcts with minimal morbidity.



LUCAS P. NEFF, Maj, USAF, MC (PI)

24 Aug 2015

(Date)

W. DOUGLAS BOYD, M.D. (PI)

25 Aug 2015

(Date)

Attachment 1

Defense Technical Information Center (DTIC) Abstract Submission

This abstract requires a brief (no more than 200 words) factual summary of the most significant information in the following format: Objectives, Methods, Results, and Conclusion.

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Grant Number:_____

From:_____

****If you utilized an external grant, please provide Grant # and where the grant came from. Thank you.**